CMSS Presents:

Reflecting on Our Covid-19 Failures – A New Vision for Integrated Registries

July 17, 2020 | 1:30 – 3:00 pm ET
CMSS WEBINAR SERIES

Advancing Clinical Registries to Support Pandemic Treatment and Response

The series will address key questions related to the rapid development, deployment and implementation of Covid-19 focused clinical registries and clinical repositories by specialty societies and academia.

SUMMER 2020 | FREE TO ATTEND
Today’s Webinar:

Reflecting on Our Covid-19 Failures – A New Vision for Integrated Registries

CMSS WEBINAR SERIES
Advancing Clinical Registries to Support Pandemic Treatment and Response

Panelists:

Elizabeth Garrett-Mayer, PhD
Division Director, Biostatistics and Research Data Governance; Center for Research and Analytics (CENTRA), American Society of Clinical Oncology

Clifford Ko, MD, MS, MSHS, FACS, FASCRS
Director, Division of Research and Optimal Patient Care, American College of Surgeons; Vice Chair and Professor of Surgery and Health Services, University of California, Los Angeles (UCLA)

Greg Martin, MD, MSc
Professor of Medicine, Emory University; School of Medicine, Executive Associate Division Director, Division of Pulmonary, Allergy, Critical Care, and Sleep Medicine; President-Elect, Society for Critical Care Medicine

Moderator:
Helen Burstin, MD, MPH, MACP
Chief Executive Officer
Council of Medical Specialty Societies (CMSS)

Michael Howell, MD, MPH
Principal Scientist
Google
REFLECTING ON OUR COVID-19 FAILURES – A NEW VISION FOR INTEGRATED REGISTRIES

Clifford Ko
Professor of Surgery and Health Services, UCLA
Director, Quality Division, American College of Surgeons
The American College of Surgeons

- Largest surgeon membership organization (80,000+ members)
- 100+ year history – founded on principles of quality and education
- Quality Division: largest division in the ACS
  - ~3000 hospitals in the US participate in one or more American College of Surgeons Quality Programs.
  - 15 Accreditation/Verification Programs (e.g. Trauma Centers Program, Cancer Center).
  - Seven Clinical Registries (e.g. National Surgical Quality Improvement Program).
Why good data are essential

- INFORMATION
- INVESTIGATION
- IMPROVEMENT
- WITHOUT DATA, WE ARE BLIND
- GARBAGE IN, GARBAGE OUT
At start of the pandemic...

◦ International studies showed extremely poor surgical outcomes.
◦ In the U.S., non-emergent operative care was triaged to conserve resources.
◦ Many hospitals didn’t know their CV-19 numbers nor outcomes – operative and non-operative.
◦ Request to ACS: help organize data collection
◦ ACS developed two things:
  1. Put CV-19 variables into current registries (e.g. NSQIP, trauma)
  2. Created a “basic” CV-19 registry
• Released April 2019
• All Covid patients (operative, non operative)
• Free
• Hospital-based (inpatients)
• Registrar collected
• IRB approved
• International
• Variables: Patient Demographics, Presenting Symptoms, Comorbidities, Treatments, Outcomes
• ~10,000 patients, 30 states
Good, however…

- Are the data providing: (1) enough clinical care and epidemiologic information, (2) adequate for investigation, (3) helping us improve?

Not really, particularly if we agree the pandemic is ongoing (and worsening in some areas)
Issues to address:

- Why are we collecting? What are the questions being answered? What are the questions we will need to answer?
- Settings - community, hospital, combinations
- Collection - case identification/ascertainment, automation
- Variables – accuracy, standardization, parsimony, related to aims, adding things later?
- Analysis – Who? How? Coordination?
- Timeliness
- Integration/Merging of registries – what’s possible?
Overarching Questions

1. If the pandemic is going to persist for awhile, what lessons (good and bad) have we learned in these past few months re: data collection, analysis, reporting, and actionable improvement?

2. What things can we do to do better?
ASCO Survey on COVID-19 in Oncology (ASCO) Registry

Liz Garrett-Mayer, PhD
Division Director, Biostatistics and Research Data Governance
Center for Research and Analytics
American Society of Clinical Oncology

CMSS Webinar Series
July 17, 2020
Why ASCO?

- National medical emergency → Opportunity for ASCO to assist the oncology community by gathering information

- Critical need to capture and analyze data on clinical care

- Objectives:
  - Analyze distribution of symptoms and severity of COVID-19 among people with cancer
  - Examine impact of COVID-19 on cancer treatment and outcomes
  - Document adaptations of cancer care to the pandemic
Patients of Interest

- Confirmed COVID-19 Diagnosis **and**
- In active anti-cancer treatment
  - Initiating treatment for new diagnosis
  - Clinically evident cancer receiving anti-cancer treatment
  - Disease-free, but receiving any type of adjuvant therapy within 1 year after surgical resection
  - Clinically evident cancer receiving supportive care only
Practice Expectations

- Execute agreement with ASCO
  - Option to use central IRB review
- Complete survey about practice changes
- Provide baseline information on patients with cancer and COVID-19
  - Medical history and risk factors
  - Cancer status and treatment plan at time of COVID-19 diagnosis
  - COVID-19 diagnosis, symptoms and treatments
- Provide updates about COVID-19 and cancer outcomes and treatment changes over time
  - No consent from patients required
  - Limited dataset, using patient zip code and date of birth to link follow-up data
Data Collection

- Sought input from collaborator from Saudi Arabia with experience from MERS outbreak June 2015 (Dr. Abdul-Rahman Jazieh)
- REDCap forms completed as survey
- Two options:
  - Submit data directly to ASCO database
    - ASCO will de-identify data and provide practice’s data back to practices for their own use
  - Collect data locally using “cloned” REDCap project
    - Practices send or upload data to ASCO at monthly intervals
- Forms can be found online:
ASCO Registry Overview

- Opened April 10

- Information through 7.16.2020

- Enrolled: 41 practices in 23 states
  - Continuing to accrue practices: 100+ interested
  - Targeting outreach to hotspot areas

- Approximately 175 patients (excluding those collected in local REDCap instances)
Inferences and Availability

- Steering Group formed to provide guidance
  - Use of data
  - Changes to data collected
  - Analyses to perform in short and long term

- Plan to release reports periodically starting in early September

- Data will be made available to external researchers in 2021
Coordination and Potential Collaborations

American Society of Hematology
- Data from patients with hematologic malignancies, collection by physicians at single point in time

COVID-19 and Cancer Consortium (CCC19) Registry
- De-identified data collected at the physician level
- One-time submission with option for follow-up data

COVID-19 in patients with thoracic malignancies (TERAVOLT)
- Global consortium

St. Jude’s
- Global consortium for COVID-19 in childhood cancers

Other countries/regions
- Brazil
- Mexico
- Saudi Arabia
- European registry for neuroendocrine neoplasms
Thanks to Participating Practices

- AIS - Cancer Center - Bakersfield (CA)
- Augusta University (GA)
- Baptist Clinical Research Institute (TN)
- Baptist Health Madisonville (KY)
- The Cancer Team - Bellin Health (WI)
- Carolina East Medical Center (NC)
- CMH/OHSU Knight Cancer Center (OR)
- Emory University (GA)
- Florida Cancer Specialists and Research Institute (FL)
- Florida Precision Oncology, a Division of 21st Century Oncology (FL)
- Fox Chase Cancer Center (PA)
- Gene Upshaw Memorial Tahoe Forest Cancer Center (CA)
- Good Samaritan Hospital (OR)
- Goshen Center for Cancer Care (IN)
- Great Lakes Cancer Management Specialist (MI)
- Greater Baltimore Medical Center (MD)
- Hartford Healthcare Cancer Institute (CT)
- Helen Diller Family Comprehensive Cancer Center, University of California, San Francisco (CA)
- Hematology Oncology Associates of Central New York (NY)
- Illinois Cancer Care (IL)
- Lakeland Hospitals (FL)
- Levine Cancer Institute, Atrium Health (NC and SC)
- LifeBridge Health, Inc. (MD)
- Michiana Hematology Oncology (IN)
- Nebraska Cancer Specialists (NE)
- Nebraska Hematology-Oncology (NE)
- NorthShore University Health System (IL)
- Oncology Hematology Care, Inc. (OH)
- Penn Medicine Lancaster General Health - Ann B Barshinger Cancer Institute (PA)
- Penn Medicine Princeton Oncology (NJ)
- PIH Health (CA)
- Sarah Cannon Research Institute at HealthONE (CO)
- Sarah Cannon Research Institute/Florida Cancer Specialists & Research Institute, LLC (FL)
- Sarah Cannon Research Institute/MidAmerica Oncology Associates, LLC (KS)
- Sarah Cannon Research Institute/Tennessee Oncology, PLLC (TN)
- Tufts Medical Center (MA)
- University of Kansas Medical Center (KS)
- The University of North Carolina at Chapel Hill (NC)
- The University of Pennsylvania (PA)
- Virginia Cancer Institute (VA)
- Virginia Cancer Specialists (VA)

Enrolled practices as of July 16, 2020
Thanks to ASCO Volunteers and Staff

Principal Investigator:
- Richard L. Schilsky, FACP, FSCT, FASCO

Volunteers
- Howard A. Burris, III, MD, FACP, FASCO
- R. Donald Harvey III, PharmD, FCCP, FHOPA
- Edward S. Kim, MD, FACP, FASCO
- Heidi D. Klepin, MD, MS
- Abdul-Rahman Jazieh, MD, MPH
- Kathryn F. Mileham, MD, FACP
- Grzegorz S. Nowakowski, MD
- Alexander I. Spira, MD, PhD, FACP
- Jaap Verweij, MD, PhD, FASCO
- David M. Waterhouse, MD, MPH

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- Rachel Martin
- Mary Gleason Rappaport, APR
- Melinda Kaltenbaugh, MBA
- M. Kelsey Kirkwood, MPH
- Andrea S. Clay
- Gina Grantham

www.asco.org/asco-coronavirus-information
VIRUS COVID-19 Registry: Viral Infection and Respiratory illness Universal Study

Greg Martin, MD, MSc
Professor of Pulmonary and Critical Care Medicine, Emory University
President-Elect, Society of Critical Care Medicine

@covid19registry
#SCCMDiscovery
Why a COVID-19 Registry?

• Our members:
  • The Society of Critical Care Medicine encompasses a diverse multi-professional workforce in more than 100 countries dedicated to excellence and consistency in the practice of critical care

• Our patients
  • Critically ill and injured patients require timely and high quality life-sustaining care throughout the course in the ICU: **Right Care, Right Now**

• Our mission
  • To secure the highest quality care for all critically ill and injured patients
We Failed Once – Never Again!

An infection wipes out an entire village in northeastern China
(3000 BC, “Hamin Mangha”)

Plague of Athens: 430 BC (killed 100K in ancient Greece)
Plague of Justinian: 541-542 AD (killed 10% of the world’s population)
The Black Death: 1346-1353 (killed 50% of Europe’s population)
Great Plague of London: 1665-1666 (100K deaths, 15% of London)

Influenza pandemic: 1889-1890 (1M deaths)
Spanish flu pandemic: 1918-1920 (100M deaths)
Asian flu pandemic: 1957-1958 (1.1M deaths)
We Failed *Once—Never Again!* 

2003: SARS-CoV-1

2009: H1N1 Influenza

2012: MERS

2014: Ebola
Never Again!

- Syndrome Definitions..
- Data Points..
- Central IRB..
- Legal Agreements..
Never Again!
2020

• Learning from those earlier failures, SCCM Discovery began creating C2D2, the Critical Care Data Dictionary, to harmonize critical data definitions for rapid deployment and data collection.

• We sought to automate data collection wherever possible, using middleware for direct capture of the data points from Electronic Health Records (EHR).

• We planned to organize hundreds of ‘sleeping nodes’ of academic and community hospitals across all 10 HHS regions, to be activated for data collection within hours of an event.
Project Description

• VIRUS is a cross-sectional, observational study and registry of adult and pediatric patients who were admitted to a hospital with COVID-19 confirmed disease or high clinical suspicion
• Only de-identified data collected and used for analysis
• Data collection for patients hospitalized after January 2020

Project Inception

- We optimized the scope of SCCM Discovery C2D2 workgroup and rapidly deployed the VIRUS COVID-19 Registry
  - Plans and opportunity to participate were shared through email and social media channels
  - Within one week, 170+ sites signed up worldwide (140+ USA)
- After all research/legal/administrative approvals, data collection started at the first 10 sites on 3/31/2020
# Data Elements

<table>
<thead>
<tr>
<th>Data Collection Instrument</th>
<th>Day 0</th>
<th>Day 1</th>
<th>Day 2</th>
<th>Day 3</th>
<th>Day 4</th>
<th>Day 5</th>
<th>Day 6</th>
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</thead>
<tbody>
<tr>
<td>Core Data I (Inclusion, Testing, Trials, Location, Admin)</td>
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<td>Core Data II (Demographics, Symptoms, Premeds, History, Diagnosis)</td>
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<td>Core Data III (Microbiology, Misc Tests)</td>
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<td>Core Data IV (Daily-Imaging, MV)</td>
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<td>Core Data V (Daily-Processes of Care, VAP Bundle)</td>
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<td>Core Data VI (Daily-Fluid, Vasopressors, Other Meds)</td>
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<td>Core Data VII (Outcomes)</td>
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<tr>
<td>Enhanced Data 1 (Daily-Vitals, Neuro exam &amp; Labs)</td>
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<td>Enhanced Data 2 (Daily SOFA, PELOD, Events)</td>
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<tr>
<td>Full Data A (APACHE II)</td>
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<tr>
<td>Full Data B (Cardiac Echo, ECG)</td>
<td>✔</td>
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<tr>
<td>FEMA Data Z (ONLY for Co-venting patients)</td>
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<tr>
<td>Pediatrics Data P (FSS, PRISM)</td>
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</table>
Subject Enrollment in Registry

VIRUS Weekly Enrollment as of July 12, 2020

Week 1 (April 3)
Week 2 (April 10)
Week 3 (April 17)
Week 4 (May 1)
Week 5 (May 8)
Week 6 (May 15)
Week 7 (May 22)
Week 8 (May 29)
Week 9 (June 5)
Week 10 (June 12)
Week 11 (June 19)
Week 12 (June 26)
Week 13 (July 3)
Week 14 (July 10)
Week 15 (July 17)

No. of Patient Enrolled

18
222
1597
2407
3437
4510
5131
6616
7789
8423
9121
9886
11216
14097
14997

Weeks and enrollment numbers are approximate and subject to change.
### VIRUS Dashboard

**Who sought help**

<table>
<thead>
<tr>
<th>Gender</th>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>53%</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>47%</td>
<td></td>
</tr>
<tr>
<td>Missing</td>
<td>13%</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Race</th>
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</thead>
<tbody>
<tr>
<td>White Caucasian</td>
<td>53%</td>
<td></td>
</tr>
<tr>
<td>Black or African American</td>
<td>28%</td>
<td></td>
</tr>
<tr>
<td>Asian American</td>
<td>7%</td>
<td></td>
</tr>
<tr>
<td>American Indian or Alaska Native</td>
<td>1%</td>
<td></td>
</tr>
<tr>
<td>East Asian</td>
<td>1%</td>
<td></td>
</tr>
<tr>
<td>West Asian (Arabic)</td>
<td>1%</td>
<td></td>
</tr>
<tr>
<td>Mixed</td>
<td>18%</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>12%</td>
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<tr>
<td>Missing</td>
<td>12%</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Ethnic Group</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Non Hispanic</td>
<td>66%</td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>22%</td>
<td></td>
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<tr>
<td>Unknown</td>
<td>7%</td>
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</tr>
<tr>
<td>Not Specified</td>
<td>5%</td>
<td></td>
</tr>
<tr>
<td>Missing</td>
<td>23%</td>
<td></td>
</tr>
</tbody>
</table>

### What type of support have patients received

<table>
<thead>
<tr>
<th>Type of Support</th>
<th>Percentage</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mechanical Ventilation</td>
<td>29%</td>
<td>8284</td>
</tr>
<tr>
<td>Non-invasive Ventilation</td>
<td>11%</td>
<td>8284</td>
</tr>
<tr>
<td>High-flow Nasal Oxygen (HFNO)?</td>
<td>15%</td>
<td>8284</td>
</tr>
<tr>
<td>Dialysis</td>
<td>7%</td>
<td>7550</td>
</tr>
<tr>
<td>Extracorporeal Membrane Oxygenation (ECMO)?</td>
<td>2%</td>
<td>5656</td>
</tr>
</tbody>
</table>

### What happened to the patients

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Percentage</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mechanical Ventilation Duration</td>
<td>9 days (Median)</td>
<td>N: 1977</td>
</tr>
<tr>
<td>ICU Length of Stay</td>
<td>7 days (Median)</td>
<td>N: 3722</td>
</tr>
<tr>
<td>ICU Discharge</td>
<td>53% Discharged Alive</td>
<td>N: 7545</td>
</tr>
<tr>
<td>Hospital Length of Stay</td>
<td>7 days (Median)</td>
<td>N: 7545</td>
</tr>
<tr>
<td>Hospital Discharge</td>
<td>80% Discharged Alive</td>
<td>N: 5965</td>
</tr>
</tbody>
</table>

### Top 5 Signs and Symptoms experienced by Patients

<table>
<thead>
<tr>
<th>Sign</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dyspnea/Shortness of Breath</td>
<td>64%</td>
</tr>
<tr>
<td>Fever</td>
<td>63%</td>
</tr>
<tr>
<td>Cough - Dry</td>
<td>40%</td>
</tr>
<tr>
<td>Myalgia Or Fatigue</td>
<td>35%</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>20%</td>
</tr>
<tr>
<td>Missing</td>
<td>59%</td>
</tr>
</tbody>
</table>

### Top 5 Comorbidities

<table>
<thead>
<tr>
<th>Comorbidity</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypertension</td>
<td>55%</td>
</tr>
<tr>
<td>Diabetes (DM)</td>
<td>32%</td>
</tr>
<tr>
<td>Obesity</td>
<td>21%</td>
</tr>
<tr>
<td>Chronic Kidney Disease</td>
<td>14%</td>
</tr>
<tr>
<td>Coronary artery disease</td>
<td>12%</td>
</tr>
</tbody>
</table>

**https://sccmcovid19.org**

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**DISCOVERY™**

The Critical Care Research Network
Strategy for Dissemination

For dissemination, SCCM has a comprehensive dissemination plan:

- VIRUS dashboard
- Publications and member facing articles
- Collaborative news releases and webcast to critical care community and beyond
- Social media campaigns
- Dissemination through the Critical Care Societies Collaborative

(PointClickCare: Data on long term care and nursing home facilities)
Current Status

The Society of Critical Care Medicine Discovery Network Viral Infection and Respiratory Illness Universal Study (VIRUS) provides an example of a rapidly deployed, international, pandemic registry that seeks to provide near real-time analytics and information regarding intensive care treatments and outcomes for patients with Covid-19

- Dashboard - https://sccm covid19.org/
- Cohort Explorer - under development
- Ancillary Studies – 68 proposals received
- Collaborations completed – ACR, PointClickCare
- Manuscripts – 1 published, 2 in development/review
Lessons Learned

Strategies that work:

✓ Meaningful collaboration, data harmonization
✓ Strong social media presence / networking
✓ Rapid IRBs approval / DUAs signing
✓ A daily reminder to focus on the goals of the registry—ICU practices, physiology, and outcomes for patients with COVID-19

Challenges:

➢ Resource limitations (project and study sites)
➢ Scope creep
➢ Political barriers to participation/data harmonization
Funding & Collaboration

The Discovery VIRUS COVID-19 Registry is funded by the Gordon and Betty Moore Foundation. With additional support from Mayo Clinic Ventures, the VIRUS Registry was able to secure funding from Janssen Research & Development to support VIRUS Registry infrastructure and critical seed funding to additional sites for data automation and data entry.

Thank you to all our partners and collaborators:

• Mayo Clinic
• Lyntek Medical
• nference
• American College of Radiology – VIRUS Imaging Partner
• PointClickCare Technologies – Providing de-identified patient data for nursing and long term care facilities
Contact US

@covid19registry
#SCCMDiscovery

kashyap.rahul@mayo.edu
vkumar@sccm.org
greg.martin@emory.edu
Perspectives on how technology can move the field forward

Michael Howell, MD, MPH
Principal Scientist, Google
Questions & Answers

Please submit all questions through the question box.
Summary & Evaluation

• Thank you to all our panelists.
• A recording of the webinar will be available on the CMSS website in the coming weeks.
• Please compete a short evaluation following the webinar.
• For more information, contact info@cmss.org.
Advancing Clinical Registries to Support Pandemic Treatment and Response

The series will address key questions related to the rapid development, deployment and implementation of Covid-19 focused clinical registries and clinical repositories by specialty societies and academia.

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CMSS WEBINAR SERIES
Advancing Clinical Registries to Support Pandemic Treatment and Response

Upcoming Webinar:

Deploying Cloud-based Platforms and Analytic Tools to Support Covid-19 and Beyond

Aug. 6 | 12:00 - 1:30 pm ET

Moderator:

William J. Marks, Jr
MD, MS-HCM
Head of Clinical Science & Head of Neurology, Verily Life Sciences;
Adjunct Clinical Professor of Neurology & Neurological Sciences, Stanford University School of Medicine

Panelists:

David Glazer
Engineering Director
Verily Life Sciences

Andrea Ramirez, MD
Assistant Professor of Medicine,
Vanderbilt University of Medicine

Chris Treml
Director of Operations, Data Science Institute, American College of Radiology

Host:

Helen Burstin, MD, MPH, MACP
Chief Executive Officer
Council of Medical Specialty Societies (CMSS)